FILED
DEC 2 8 2006

(2)

No. 06-693

IN THE

Supreme Court of the United States

FALKO-GUNTER FALKNER, GEORG HOLZER, and FRIEDRICH DORNER,

Petitioners,

v.

STEPHEN C. INGLIS, MICHAEL E.G. BOURSNELL, and ANTHONY C. MINSON,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF

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STATEMENT PURSUANT TO RULE 29.6

Petitioners' corporate disclosure statement was set forth at page *ii* of the Petition for a Writ of Certiorari, and there are no amendments to that statement.

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35 U.S.C. § 112 ..... 2, 7

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Vernon M. Winters & Elizabeth S. Weiswasser, *The Written Description Requirement: Ripe Enough? Or Is More Percolation Required?* 51 Fed. Law. 20 (2004) 2

INTRODUCTION

The *Falkner v. Inglis* decision should not stand because the Federal Circuit has not heeded the established jurisprudence of this Court regarding the disclosure requirements that are incumbent on all patent applicants. Should this decision stand, patent applicants will be permitted to obtain patents that do not promote the progress of science, that claim subject matter outside of their discovery, and that are not supported by a description of the invention and of how to make and use it in the requisite full, clear, concise and exact terms. Absent review and a reversal, this decision will permit the issuance of patents that are not in compliance with the U.S. Constitution and the patent laws. This decision is a direct result of the continuing conflict at the Federal Circuit on the scope and nature of the disclosure requirements for patent applicants.

Writing as if the dispute among the Federal Circuit judges on the issue of written description did not exist, Respondents in opposition refer to an "alleged 'conflict.'"[1] As pointed out in the Petition, however, no fewer than five Federal Circuit judges have strongly voiced their dispute, and their conflict has drawn the attention of scores of academics and practitioners who have written about the conflict. For example:

> As to this requirement, a debate has been brewing in the U.S. Court of Appeals for the Federal Circuit – the appellate court responsible for appeals in all cases – over whether the patent statute contains a separate "written description"

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1. See footnote 2 at page 3 of Respondent's Brief in Opposition to Petition for Writ of Certiorari ("Opposition Brief"). See also Opposition Brief at page 1: "Petitioner suggests an intra-Federal Circuit controversy concerning whether the 'written description' requirement of 35 U.S.C. § 112 is separate from the 'enablement' requirement of 35 U.S.C. § 112."

> requirement, or whether the description requirement is simply part and parcel of the requirement that the patent enable those in the art how to make and use the invention. The debate has been particularly fierce in the area of patents directed to pharmaceutical and biotechnology inventions. Recently, over vigorous dissenting opinions, the court has declined to address this issue as en banc court, leaving open the question of whether the Supreme Court will weigh in.

Petition at page 20, *quoting* Vernon M. Winters & Elizabeth S. Weiswasser, *The Written Description Requirement: Ripe Enough? Or Is More Percolation Required?* 51 Fed. Law. 20 (2004).

Respondents next allege that the Petition "does not clearly articulate the alleged 'conflict'" nor spell out the connection between this case and the "alleged conflict." Opposition Brief at page 3, footnote 2. Again, they are incorrect. The foregoing passage, the cited dissents, and numerous other parts of the Petition all make clear how the conflict over whether there is a separate written description requirement or whether it is merely part of the enablement applies to this case.

In Petitioner's view, there can be no dispute as to what the panel did. By conflating the written description and enablement requirements of 35 U.S.C. § 112, the panel effectively eliminated the requirement of this Court, the statute, and other panels of the Federal Circuit that an application as filed must contain a written description of the invention and how to make and use an invention in full, clear, concise and exact terms. Rather, the panel subscribed to the competing view that there is only an "enablement requirement" that permits virtually every detail of a claimed invention to be filled in by hindsight citation to "accessible

literature sources[2]" that provide published compositions[3] that are not identified nor suggested in the application. The panel's pronouncement of a new 'written description requirement' for biotechnology inventions radically alters the Constitutionally-mandated bargain between patentees and the public from one that will "promote the Progress of Science" to one that will not. The specific points raised by Respondents are addressed below.

NEW POINTS RAISED BY RESPONDENT

The ongoing, tumultuous dispute at the Federal Circuit

At pages 3-5 of their Opposition Brief, Respondents contend that the conflict at the Federal Circuit on written description has no bearing on this case. Respondents support their position by citing to a lack of dissent in the Federal Circuit decision and the denial of the petition for rehearing and rehearing *en banc* issued in the late summer of this year. Respondents, however, did not address the adverse impact the Federal Circuit's conflicting written description jurisprudence has on the patent system.

In response, Petitioners first reiterate that the Federal Circuit panel stated that the Board of Patent Appeals and Interferences ("the Board") had not properly articulated the written description standard in rendering its decision. App. 15a. While the panel dismissed this error as being harmless, a legal inquiry that starts from a wrong premise is exceedingly unlikely to be proper.

Second, as noted by Respondents at page 4, the *Falkner v. Inglis* decision was authored by Circuit Judge Gajarsa, who

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2. App. 21a.

3. Here, the compositions would be poxvirus essential genes as they exist in nature. Importantly, not even the literature sources disclose which essential regions to use to make the contested poxvirus vaccine invention nor the complementing cells needed to grow the poxviruses. See Petition at page 24, fn.19.

has joined in dissents arguing that a separate written description requirement creates confusion and is an ill-defined doctrine. *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1326 (Fed. Cir. 2004), *cert. denied*, 543 U.S. 1015 (2004); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 982 (Fed Cir. 2002). The *Falkner v. Inglis* decision is nothing less than a direct repudiation of the competing ideology[4] at the Federal Circuit. Hence, litigants are now confronted with directly competing ideologies embodied in diametrically contrary decisions. Federal Circuit panels of either or mixed ideologies are now fully armed with competing precedential decisions upon which to support their particular views.

In this case, the panel's decision did not explain whether Inglis provided a full, clear, concise and exact description of a poxvirus vaccine invention, and of how to make and use it. Rather, the decision focused on general types of description that are not needed in patent applications.[5] When every type of description discussed by the panel is missing in the Inglis priority applications, and there is no alternative disclosure of any detail concerning poxvirus vaccines to make up for their absence, it can be fairly said that the panel did not believe that Respondents needed to provide in their applications a written description of the poxvirus vaccine

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4. The competing ideology at the Federal Circuit requires a detailed written description of the invention in addition to an enabling disclosure, whereas the ideology prevailing here requires only enablement, and not a full, clear, concise and exact written description of the invention. Enablement, however, can be supplemented by alleged outside knowledge in the field. By its very nature, this latter ideology is quite susceptible to hindsight 'reinvention' of patent applications.

5. The Federal Circuit panel opined that (1) examples are not required, (2) there need not be an actual reduction to practice, which refers to invention actually made and shown to work, and (3) recitation of known structure is not required. App. 17a-21a.

invention and of how to make and use it in "full, clear, concise, and exact terms." In other words, this section of the patent laws has been effectively removed as a requirement for patent applicants.

Finally, Respondents on pages 3-4 argue that the Federal Circuit summarily dismissed the petition for rehearing and rehearing *en banc* and saw no urgency in that petition. Such an argument is speculative, and does not tell the whole story. It is beyond dispute that the Federal Circuit has not clarified its law on written description in an *en banc* manner in any case, and will not provide Petitioner with the relief sought here to correct the errors made by the panel. Indeed, one Federal Circuit Judge has stated, "I do not believe that every error by a panel is enbancable. A panel is entitled to err without the full court descending upon it." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 469 F.3d 1039, 1043 (Fed. Cir. 2006) (Lourie, J., concurring) (discussing the denial of a petition for rehearing *en banc* on a claim construction issue). What is a patent holder to do in such situations?

Petitioners' characterization of the Inglis applications was accurate

At pages 5-6, Respondents argue that Petitioners have mischaracterized the Inglis priority applications. Respondents cite to their alleged generic disclosure to all viruses, their herpesvirus disclosure and examples, their three passages mentioning poxviruses, and purported findings by the Board. Petitioners believe these issues were identified and accurately discussed on pages 8, fn 7; 11-13 and 23-25 of the Petition to this Court. In opposition, Respondents cite to no disclosure beyond the two sentences quoted in the Petition. As stated before, the first sentence referenced a type of poxvirus (*i.e.*, vaccinia) as a possible starting material for deriving a vaccine in the future, and the second sentence expressly acknowledged that a poxvirus vaccine had not been made:

> As another example the virus may be derived from an orthopox virus [types of poxviruses], for example, vaccinia virus, which again may comprise a heterologous sequence encoding an immunogen derived from a pathogen.

Inglis PCT application at page 6, line 26 to page 7, line 4. A420-21.

> No vaccinia virus [a type of poxvirus] with a deletion in an essential gene has yet been produced, but such a virus, deleted in an essential gene as described above, with its complementing cell for growth, would provide a safer version of this vaccine vector.

Inglis PCT application at page 15, lines 1-5. A429.

Respondents provided nothing more than this.

The decision on enablement

Respondents' argument is set forth at pages 6-11 of their Brief. Respondents argue that enablement was satisfied by the stipulated high level of skill in the poxvirus art, the contents of the prior art that need not be disclosed in a patent application, and a detailed disclosure of herpesvirus vaccines. Respondents allege that their prosecution statement[6] concerning the differences between herpesviruses and poxviruses was not relevant and was belatedly presented. Respondents' rebuttal argument fails, however, because neither the Board nor the Federal Circuit panel addressed this prosecution statement.

The important point here is that Respondents seek to rely upon "accessible literature sources" outside of their application to extrapolate herpesvirus teachings into poxvirus teachings, and thereby provide descriptive support for a patent grant to the contested poxvirus vaccine invention.

6. See Petition at pages 26-27.

Respondents' entire case thus is based upon an allegation of what the skilled person would have been able to,[7] rather than upon what Respondents actually did and did not disclose. To summarize, the prior art and the skill in the art are not part of the patent specification. Herpesvirus vaccines are not the invention in interference, and herpesviruses were represented by Respondents to be significantly different from poxviruses. What the patent statute calls for here is disclosure in the specification of the poxvirus vaccine invention and how to make and use it in full, clear, concise and exact terms. The Constitution calls for patent applicants to be awarded only with patents to their discovery, not the discoveries of others, in order to promote the progress of science. The award to Respondents here is based on a wholesale reliance on information in the prior art combined with disclosure of a different invention, which satisfies neither the Constitution nor 35 U.S.C. § 112.

The decision on written description

Respondents discuss written description on pages 11-18 of their Brief. At page 12, Respondents urge that the Board and the Federal Circuit panel carefully reviewed the entire record, which is open only to speculation by the parties. What is clear, however, is that (1) the Board issued a non-anticipation holding, unappealed by Respondents, that is diametrically opposed to the judgment affirmed by the Federal Circuit, and (2) the Federal Circuit panel did not discuss the impact of this Board holding in its decision.[8]

7. *See U.S. Industrial Chemicals v. Carbide & Carbon Chemicals Corp.*, 315 U.S. 668, 677-78 (1942) (noting that if an invention was as broad as professed in litigation, "[t]he inquiry at once arises, if this were so, why he did not say so" in the patent application.). Neither the Federal Circuit nor the Board undertook such an inquiry.

8. The parties agree that the Federal Circuit did not address this holding, but differ on the reason why. See Petition at pages 11, 12 and 22; Opposition Brief at pages 17-18.

Respondents try to explain away the Board's non-anticipation holding as being premised on the Board not finding that the Inglis PCT application described a "heterogene" encoding an antigen. See Respondents' Opposition Brief at 17. Although Respondents do not explain what a heterogene is, Petitioners presume Respondents are referring to a gene from a foreign source, such a bacterial gene or another type of virus.[9]

More importantly, however, Respondents' story cannot be squared with the Board's decision. In rendering its non-anticipation decision, the Board focused on the citations provided by Respondents. The Board found that the citations provided by Respondents were directed to the poxvirus prior art, not the poxvirus vaccine invention of the interference. Indeed, the Board stated:

> Nevertheless, the disclosure at page 14 is directed to the ability of vaccinia virus, a particular, well-known poxvirus, to carry and express genes from various pathogens" and the use of a vaccinia virus modified to carry and express genes from various pathogens as an effective vaccine in animals. Inglis has failed to explain why we should construe the referenced disclosure as being directed to a defective poxvirus lacking a function imparted by an essential region of the parental poxvirus. Moreover, the remainder of the context of the cited portion of the reference discusses "the reluctance to use an unmodified vaccinia virus on large scale in humans." We do not understand that

9. There is no requirement for a "heterogene" in the poxvirus vaccine invention of the interference, rather its presence is purely optional. See Petition at page 8, fn.8. The count, which defines the contested invention, does not expressly or implicitly require a "heterogene." Moreover, Petitioners' claim 1 (which is part of the count) and the Board decision does not expressly or implicitly require or discuss a "heterogene."

> an "unmodified vaccinia virus" would be understood to mean a "defective poxvirus that lacks a function imparted by an essential region of its parental poxvirus." App. 63a.

This discussion is entirely consistent with Petitioners' position, namely that the Inglis priority applications discuss poxvirus prior art, but do not disclose the poxvirus vaccine invention in full, clear, concise and exact terms. Rather, the Inglis priority applications only contain the two sentences discussed above.

The Federal Circuit did not address this Board holding even though it was brought to their attention. Rather, the Federal Circuit panel quoted the language (see, e.g., page 14 of the Inglis PCT application, A428-29) discussed by the Board above. However, the panel quoted from application page 14 in order to support affirmance. App. 13a. Thus, text that the Board determined only concerned the poxvirus prior art and not the contested poxvirus vaccine invention was used by the Federal Circuit as text that disclosed the contested poxvirus vaccine invention. Logically, this situation cannot hold.

Again, absent action by this Court, Respondents' patent applications will continue to be held to both describe and not describe the poxvirus vaccine invention of the interference. Such as status should not be permitted to continue.

CONCLUSION

In sum, the Federal Circuit panel would award a patent to applicants who provide nothing more than a two sentence wish for others to conceptualize, design and make the contested poxvirus vaccine invention. The Federal Circuit panel bases this award on patent applications that the Board expressly found did not describe poxvirus vaccines, a determination which Respondents have not appealed. Rather, Respondents' patent applications concern herpesvirus, a technology which Respondents represented to the Patent Office does not pertain to poxvirus. The decision of the Federal Circuit panel would not award Respondents with a patent to their discovery, but would rather award Respondents with a patent to the discovery of others, namely Petitioners.

Respectfully submitted,

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